Rejection of Claims 1-2, 7-12, 23-27 and 56-58 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-2, 7-12, 23-27 and 56-58 have been rejected under 35 U.S.C. § 112, second paragraph, as it is said that they are indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Claim 1 is said to be vague and indefinite in not having clear and positive prior antecedent basis for the term "gene" in step (b). Claim 1 has been amended to clarify antecedent basis.

Claim 7 is said to be vague and indefinite in that "growth rate" is unclear in step (c). Claim 7 has been amended to make clear that the it is "growth rate of the cells" being referred to.

Claim 11 is said to be vague and indefinite in that the outcome of the claim does not match the result stated in the preamble. Claim 11 has been amended to make it clear that the steps achieve the result recited in the preamble.

Claim 12 is said to be vague and indefinite in that there is said to be no clear and positive antecedent basis in the claim for the term "infection." Claim 12 has been amended to make its terms consistent with a method of identifying an inhibitor of growth of cells. The method of Claim 12 can be used to identify an inhibitor of infection. However, this is only one example of how the method of Claim 12 can be applied. Page 27, line 12 to page 30, line 10 of the written description provides an extensive discussion of the steps of the method of Claim 12, and how they can be applied not only to identifying an inhibitor of growth of an infectious organism, but also to identifying an inhibitor of growth of other types of cells, for example cancer cells or other types of hyperproliferating cells.

Claim 23 is said to be vague and indefinite in not having a clear and positive prior antecedent basis for the term "a target cell component" in step (e). Claim 23 has been amended to clarify the relationship between the target cell component and the biomolecule which is produced in the cell. For support for this amendment, see, for example, page 5, lines 9-19 of the written description.

Claims 7-8, 10-12 and 56-58 are said to be vague and indefinite in that the claims specify "suitable" control animals or control cells. Claim 10, depending on Claim 8, does not contain the term "suitable." Independent Claims 56 and 58 do not contain the term "suitable." Claims 7, 8

11, 12 and 57 have been amended to delete the term "suitable," as the terms "control animals" and "control cells" are readily understood by persons of ordinary skill in the art.

The Exemplification section provides a number of examples of control cells and control animals, providing guidance in the choice of controls appropriate for the method. See, for example, page 41, line 20 to page 42, line 2 for the use of control cells. Example 3 (page 42, line 3 to page 43, line 10) illustrates the use of control animals for the comparison of results with test animals. The use of control animals is also discussed on page 5, line 20 to page 6, line 5 of the written description. The choice of, and use of, control cells is discussed at page 27, line 12 to page 28, line 7.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Carol A. Egner
Carol A. Egner
Registration No. 38,866
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
Dated: March 4, 2002

MARKED UP VERSION OF AMENDMENTS

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

1. (Twice Amended) A method for determining whether a biomolecule inhibits infection by a pathogen cell, comprising the steps of:

a) introducing into a test animal and into a control animal a pathogen cell comprising an exogenous regulable gene encoding the biomolecule;

b) regulating expression of the exogenous gene to produce the biomolecule in the cell in the test animal but not in the cell in the control animal; and

c) monitoring said test and control animals for signs of infection;

whereby observing fewer or less severe signs of infection in said test animal compared to signs of infection in the control animal indicates that the biomolecule inhibits infection by the pathogen cell.

7. (Twice Amended) A method for determining whether a biomolecule is a biomolecular inhibitor of growth of cells, comprising:

a) introducing into one or more test animals and into one or more suitable control animals cells having a regulable gene encoding a biomolecule;

b) regulating, in the test animals, expression of the gene to allow production of the biomolecule; and

c) monitoring said test animals for growth of the cells;

wherein observing fewer of the cells or a slower growth rate of the cells in said test animals compared to the number of the cells or growth rate of the cells in [suitable] the control animals indicates that the biomolecule is a biomolecular inhibitor of growth of the cells.

8. (Twice Amended) A method for assessing whether a biomolecule is a biomolecular inhibitor of growth of cells in a host mammal comprising:

a) constructing cells having a regulable gene encoding the biomolecule;

b) introducing the cells into test animals and into [suitable] control animals;

c) regulating, in the test animals, expression of the regulable gene to produce the biomolecule; and

d) monitoring the test animals and control animals for growth of the cells;

wherein observing less growth of the cells in the test animals than in the control animals indicates that the biomolecule is a biomolecular inhibitor of growth of the cells.

11. (Twice Amended) A method for determining whether a target component of a cell is essential for growth of said cell in an animal, comprising:

a) in cells comprising a biomolecule and a target cell component, wherein the biomolecule is a biomolecular binder of the target cell component, and wherein a gene encoding the biomolecule is regulable, regulating expression of the gene to produce the biomolecule;

b) monitoring growth of the cells in culture relative to growth of [suitable] control cells, whereby, if growth is decreased in the cells compared to growth of [suitable] the control cells, then the biomolecule is a biomolecular inhibitor of growth of the cells;

c) introducing into one or more test animals cells in which growth can be decreased compared to the control cells as determined in step b);

d) regulating expression of the gene to produce the biomolecular inhibitor of growth in the introduced cells; and

e) monitoring said test animals for inhibition of the growth of the cells;

wherein observing fewer cells or slower growth of cells in said test animals compared to cells or growth of cells, respectively, in [suitable] the control animals indicates that the target component of said cell is essential for growth of said cell in an animal.

12. (Amended) A method for identifying a biomolecular inhibitor of growth of cells, comprising:

a) in cells comprising a biomolecule and a target cell component, wherein the biomolecule is a biomolecular binder of the target cell component, and the gene encoding the biomolecule is regulable, regulating expression of the gene to allow production of the biomolecule;

b) monitoring growth of the cells in culture relative to growth of [suitable] control cells, whereby, if growth is decreased in the cells compared to growth of [suitable] the control cells, then the biomolecule is a biomolecular inhibitor of growth;

c) introducing into one or more test animals cells in which growth can be decreased compared to the control cells in step b);

d) regulating expression of the gene to allow production of the biomolecule in the introduced cells; and

e) monitoring said test animals for inhibition of the growth of the cells;

wherein observing fewer cells or slower growth of cells in said test animals compared to cells or growth of cells, respectively, in [suitable] the control animals indicates that the biomolecule is a biomolecular inhibitor of [infection] growth of cells.

23. (Twice Amended) A method for identifying a compound which is a candidate for producing a phenotypic effect in a cell, said method comprising the steps of:

a) constructing a cell comprising an exogenous regulable gene which encodes a biomolecule;

b) introducing said cell into an animal;

c) regulating expression of the gene to produce the biomolecule in the cell;

d) monitoring said cell in the animal for the phenotypic effect; and

e) identifying, if the biomolecule caused the phenotypic effect, one or more compounds that competitively bind to a target cell component to which the biomolecule binds, whereby if the compound competitively binds to the target cell component, then the compound is a candidate for producing the phenotypic effect.

57. (Twice Amended) A method for identifying one or more compounds that are candidates for binding to a target cell component in a pathogen and inhibiting infection of a mammal by the pathogen, comprising:

a) constructing a pathogen comprising a regulable gene encoding a biomolecule which binds to the target cell component;

b) regulating expression of the gene in a culture of constructed pathogen cells, thereby producing the biomolecule in the constructed pathogen cells;

c) monitoring growth of the constructed pathogen cells in culture, relative to growth of [suitable] control cells, whereby, if growth is decreased in the constructed pathogen cells, compared to growth of the control cells, then the biomolecule is a biomolecular inhibitor of growth;

d) infecting one or more test animals with the constructed pathogen, and one or more control animals with the constructed pathogen or with a control pathogen;

e) regulating expression of the regulable gene in the test animals, thereby producing the biomolecule;

f) monitoring the test animals and the control animals for signs of infection, wherein observing fewer or less severe signs of infection in the test animals than in the control animals indicates that the biomolecule is a biomolecular inhibitor of infection by the pathogen; and

g) identifying one or more compounds that compete with the biomolecular inhibitor of infection for binding to the target cell component;

whereby, if a compound competes with the biomolecular inhibitor of infection for binding to the target cell component, then the compound is a candidate for binding to the target cell component in the pathogen and inhibiting infection of the mammal by the pathogen.